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## **REMARKS**

### **A. Claim Amendments**

In view of the above amendments, claims 33-48, 50-56 and 58-70 are presently pending.

A separate sheet entitled "Version with Markings to Show Changes Made" is provided to illustrate the amendments made to claims 33, 37, 39-41, 43-47 and 50-56, the deletion of claims 1-32, 49 and 57, and the addition of claims 58-70.

Support for new claims 58-70 can be found, for example, in originally filed claims 2-14.

### **B. Response to Office Action**

Responsive to the Office Action mailed October 2, 2002 in the above matter, please consider the following response to the outstanding restriction requirement.

Restriction was required to the following allegedly distinct inventions:

- I. Claims 1-32, 43-45, 49 and 57.
- II. Claims 33-42 and 46-48.
- III. Claims 50-52 and 56.
- IV. Claim 53, in part.
- V. Claim 53, in part.
- VI. Claims 54-55.

Applicants elect the Group II claims, with traverse, for initial prosecution on the merits.

The election is respectfully made with traverse, because a search and examination of the entire application can be made without serious burden. It is noted, for example, that Groups III-VI are all classified in the same class/subclass.

Election of a single disclosed species for prosecution on the merits was also required under 35 U.S.C. 121.

Applicants hereby elect as a disclosed species a lipid molecule comprising a sphingosine base as a backbone and comprising a  $\text{S}-\text{N}=\text{O}$  group

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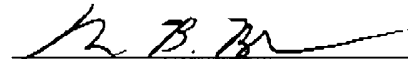
**CONCLUSION**

Applicants submit that the claims of the present invention are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 to resolve any outstanding issues.

**FEES**

The Office is authorized any required fees, including the \$110.00 fee for a one-month extension of time, to deposit account number 50-1047.

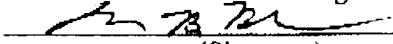
Respectfully submitted,

  
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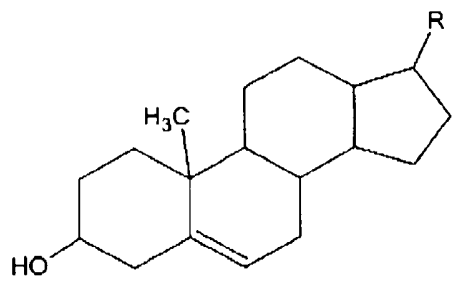
David B. Bonham  
(Printed Name of Person Mailing Correspondence)  
  
(Signature)

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Version With Markings To Show Changes MadeIN THE CLAIMS:

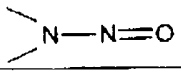
Delete claims 1-32, 49 and 57.

33. (Amended) A drug delivery system comprising a medical article and the compound of claim 1 a nitric oxide releasing compound comprising a lipid molecule selected from (a) phosphoglycerides, (b) lipid molecules having a sphingosine base as a backbone, (c) monoacylglycerols, (d) diacylglycerols, (e) glycosylacylglycerols, and (f) sterol molecules of the formula:



where R is a branched aliphatic chain of eight or more carbon atoms.

said lipid molecule comprising a nitric-oxide containing group selected from (a) a

—S—N=O group, (b) a —O—N=O group, and (c) a  group.

34. The drug delivery system of claim 33, wherein the medical article is a bandage or a patch.

35. The drug delivery system of claim 33, wherein the medical article is an intravascular medical device.

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36. The drug delivery system of claim 35, wherein the intravascular medical device is selected from a balloon catheter, an injection catheter, an infusion catheter, a stent, a stent graft, and a distal protection device.

37. (Amended) The drug delivery system of claim 33, wherein the nitric oxide releasing compound of claim 1 is provided within a polymer matrix.

38. The drug delivery system of claim 37, wherein the matrix is a biocompatible matrix selected from a stable polymer matrix and a biodegradable polymer matrix.

39. (Amended) The drug delivery system of claim 33, wherein the nitric oxide releasing compound of claim 1 is dissolved or dispersed in a solution.

40. (Amended) The drug delivery system of claim 33, wherein the nitric oxide releasing compound of claim 1 is adsorbed on a tissue-contacting surface of said medical article.

41. (Amended) The drug delivery system of claim 33, wherein the nitric oxide releasing compound of claim 1 is provided within a micelle or a liposome.

42. The drug delivery system of claim 33, further comprising a therapeutically effective amount of an auxiliary therapeutic agent selected from agents having antineoplastic activity, agents having antiproliferative activity, and agents having both antineoplastic and antiproliferative activity.

43. (Amended) A method for therapeutically administering nitric oxide to a patient comprising administering the compound-drug delivery system of claim 33 to said patient.

44. (Amended) The method of claim 43, wherein the compound-drug delivery system is administered topically.

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45. (Amended) The method of claim 43, wherein the ~~compound~~ drug delivery system is administered within the body.

46. (Amended) The method of claim 45, wherein the ~~compound~~ drug delivery system is administered by implantation.

47. (Amended) The method of claim ~~45~~ 46, wherein the ~~compound~~ is administered by medical article is an intravascular delivery device.

48. The method of claim 47, wherein the intravascular delivery device is selected from a balloon catheter, an injection catheter, an infusion catheter, a stent, a stent graft, and a distal protection device.

50. (Amended) A method of treating or preventing a condition selected from atherosclerosis and myocardial infarction in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to treat or prevent said condition.

51. (Amended) A method of treating or preventing restenosis in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to treat or prevent said restenosis.

52. (Amended) A method of treating or preventing a condition selected from peripheral vascular disease, stroke, impotence, septic shock and arthritis in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to treat or prevent said condition.

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53. (Amended) A method of treating or preventing a condition selected from cancer and bacterial infection in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to treat or prevent said condition.

54. (Amended) A method of treating or preventing a condition selected from one or more of impetigo, epidermolysis bullosa, eczema, neurodermatitis, psoriasis, pruritis, erythema, hidradenitis suppurativa, warts, diaper rash and jock itch in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to treat or prevent said condition.

55. (Amended) A method of promoting wound healing in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to promote said wound healing.

56. (Amended) A method of reducing cells present in an atherosclerotic lesion in a patient, said method comprising administering to said patient the drug delivery system of claim 33, wherein the drug delivery system comprises an amount of the nitric oxide releasing compound of claim 1 effective to reduce the cells present in said atherosclerotic lesion.

58. (Newly added) The drug delivery system of claim 33, wherein the lipid molecule is a lipid molecule having a sphingosine base as a backbone.

59. (Newly added) The drug delivery system of claim 58, wherein the lipid having a sphingosine base as a backbone is N,N,N-trimethylsphingosine.

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60. (Newly added) The drug delivery system of claim 58, wherein the lipid having a sphingosine base as a backbone is a sphingolipid.

61. (Newly added) The drug delivery system of claim 60, wherein the sphingolipid is a ganglioside.

62. (Newly added) The drug delivery system of claim 33, wherein the lipid molecule is said phosphoglyceride.

63. (Newly added) The drug delivery system of claim 62, wherein the phosphoglyceride is phosphatidylinositol or phosphatidylcholine.

64. (Newly added) The drug delivery system of claim 33, wherein the lipid molecule is said sterol compound.

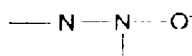
65. (Newly added) The drug delivery system of claim 64, wherein said sterol compound is cholesterol.

66. (Newly added) The drug delivery system of claim 33, wherein said nitric-oxide containing group comprises a  $\text{—S—N=O}$  moiety.

67. (Newly added) The drug delivery system of claim 33, wherein said nitric-oxide containing group comprises a  $\text{—O—N=O}$  moiety.

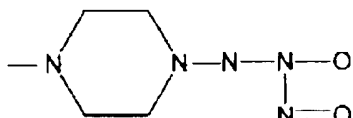
68. (Newly added) The drug delivery system of claim 33, wherein said nitric-oxide containing group comprises a  $\text{>N—N=O}$  moiety.

69. (Newly added) The drug delivery system of claim 68, wherein said nitric-oxide



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70. (Newly added) The drug delivery system of claim 69, wherein said nitric-oxide



containing group comprises a